Paper No. 25

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KIN-MING LO,
and
STEPHEN D. GILLIES

Appeal No. 1995-4389
Application 07/781,395[1]

ON BRIEF

Before WINTERS and WILLIAM F. SMITH, Administrative Patent Judges and McKELVEY, Senior Administrative Patent Judge.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal from the final rejection of claims 1, 3 through 8 and 10 through 15. Subsequent to the final rejection, those claims were canceled and replaced with

16. A method for the recombinant production and secretion of biologically active heterotetrameric immunoglobulin from a gram negative bacterium, the method comprising:

(a) providing a gram negative bacterium transformed with a DNA molecule comprising a DNA sequence encoding two polypeptide chains, said polypeptide chains together defining light and heavy chains of an immunoglobulin having a binding site for a given, preselected antigen, each said polypeptide chain further comprising an amino acid export sequence, said DNA being operationally associated with a promoter recognizable by RNA polymerase endogenous to said organism, and

(b) culturing said transformed bacterium for a time sufficient to allow expression of said DNA sequence and the export of said polypeptide chains, such that, when exported, said polypeptide chains spontaneously combine to form a biologically active heterotetrameric immunoglobulin having binding specificity for said preselected antigen.

19. A DNA molecule having a sequence encoding two polypeptide chains, said chains together defining light and heavy chains of an immunoglobulin having binding specificity for a given preselected antigen, each said polypeptide chain further comprising an amino acid export sequence.

Claim 19 stands rejected under 35 U.S.C. § 102(b) as anticipated by Better (1988)[2]. In addition, claims 16 through 18 stand rejected under 35 U.S.C. § 112, first paragraph (enablement). We affirm the prior art rejection and reverse the enablement rejection.

DISCUSSION

1. Anticipation

The examiner has set forth in the paragraph bridging pages 5-6 of the examiner's answer an explanation of how Better (1988) describes a DNA molecule

findings of the examiner in this regard. Rather, appellants' position is that the DNA molecule described by Better encodes a heterodimeric immunoglobulin instead of a heterotetrameric immunoglobulin.

Claim 19 on appeal only requires a DNA molecule that encodes (1) two polypeptide chains which together define light and heavy chains of immunoglobulin and (2) an amino acid exporting sequence for each polypeptide chain. As established by the examiner, Better (1988) teaches such a DNA molecule. Whether the DNA molecule of Better (1988) is described in the reference as producing a heterotetrameric immunoglobulin or a heterodimeric immunoglobulin is not relevant in determining the patentability of claim 19 since the claim is directed to DNA, not to a method of using DNA. Appellants have not established on this record how the DNA molecule required by claim 19 on appeal differs from that described in Better (1988).

The rejection under 35 U.S.C. § 102(b) is affirmed.

2. Enablement

We reverse this rejection since it appears to be based upon an incorrect legal standard and incomplete fact finding.

In reviewing the statement of the rejection on pages 6-11 of the examiner's answer, it appears that the examiner's main concern is that it is possible to practice the

> exclude . . . possible inoperative substances . . . . In re Dinh-Nguyen, 492 F.2d 856, 859-59, 181 USPQ 46, 48 (CCPA 1974) (emphasis omitted). Accord, In re Geerdes, 491 F.2d 1260, 1265, 180 USPQ 789, 793 (CCPA 1974); In re Anderson, 471 F.2d 1237, 1242, 176 USPQ 331, 334-35 (CCPA 1971). Of course, if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid. See, e.g., In re Cook, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971).

Here, the examiner is not concerned that one skilled in the art would have difficultly in obtaining other DNA molecules as required by claim 16 on appeal. Nor is the examiner concerned that one of ordinary skill in the art would not be able to transform gram negative bacteria with such DNA molecules. Rather, the examiner's concern is that transformed gram negative bacteria other than those exemplified in the specification might not work to form biologically active heterotetrameric immunoglobulins.

As set forth in Atlas Powder Co., supra, the fact that a claim may arguably include inoperative embodiments does not mean that the claim is non-enabled. Rather, it is only if the number of inoperative embodiments is significant that the issue arises. All we have here is the examiner's analysis that it is possible that claim 16 includes within its scope inoperative embodiments. We do not have a fact-based analysis from the examiner establishing that it would require undue experimentation from one skilled in the art to arrive at operative embodiments within the scope of claim 16 as opposed to

in that Examples 7-12 of the specification illustrate a production of a full-length antibody. The examiner did not contest this finding by appellants in the supplemental examiner's answer, yet did not reassess her position to take into account the now conceded new set of facts. Evaluating the enablement of a claim pending in a patent application based upon a consideration of less than the complete disclosure of the application is error.

The enablement rejection is reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

Sherman D. Winters Administrative Patent Judge	)
William F. Smith Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
Fred E. McKelvey, Senior Administrative Patent Judge	)

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